K053214

DEC 2 0 2005

# 510(k) Summary

Trade Name: **TheraKnit**

Common/Classification Name: Electrode, Cutaneous (84GXY) 21 CFR 882.1320

Neurotron Medical, Inc.
800 Silvia Street
West Trenton, NJ 08628
800-367-1238

Contact: Jack Guldalian, President

Prepared: August 24, 2005

## A. LEGALLY MARKETED PREDICATE DEVICES

K932299 Electro-Mesh Glove Electrode Prizm Medical, Inc.

K944487 Electro-Mesh Sock, Wrap and Sleeve Electrodes Prizm Medical, Inc.

K943009 SMD Glove, Sock and Sleeve Electrodes Scientific Medical Devices, Inc.

## B. DEVICE DESCRIPTION

The TheraKnit Garment Electrodes are conductive garments knitted from a continuous silver coated Nylon yarn into the form of gloves, socks, sleeves and flat fabric used for pads. The conductivity is derived from the silver content of the Nylon yarn. The garment electrodes are available in a variety of sizes ranging from small to extra large for gloves and small to large for socks and sleeves. The elongation property of the nylon yarn provides some elasticity which ensures firm skin contact. The devices can be used dry or wet when in contact with the skin. The entire surface of each garment electrode is very conductive having a resistance of less than 7 ohms per inch. This low resistance provides low current density with uniform current distribution.

## C. INTENDED USE

TheraKnit garment cutaneous electrodes as glove, socks, sleeves and pads are intended for use with legally marketed electrostimulation devices such as TENS and NMES to deliver stimulation current for pain relief. They can be used on body parts such as hands, feet, arms, legs, low back and shoulder for pain relief using electrostimulation.

## D. SUBSTANTIAL EQUIVALENCE SUMMARY

The TheraKnit Garment Electrode is a medical device that has the same indication, intended use and target population as the legally marketed predicate devices.

TheraKnit has the same technological characteristics as the predicate devices. Both the TheraKnit and the predicate devices are made with a silver plated nylon yarn. The resistance of the knitted garment for both TheraKnit and the predicate devices are less than 7 ohms/inch which is very low relative to the delivery of the stimulation current.

Both TheraKnit and the predicate devices receive the electrostimulation signal from a legally marketed TENS or NEMS device through a lead wire with a 0.080" pin connection connected to a snap connector on the knitted garment device.

Both TheraKnit and the predicate devices are washable and intended for single patient use.

## E. TECHNOLOGICAL CHARACTERISTICS

The TheraKnit garment electrodes are made from a silver plated nylon yarn using a conventional knitting process. The fabric is highly conductive and provides less than 7 ohms resistance per inch. The device can be used with either positive or negative polarity, a second electrode is necessary to direct the stimulator current to the target tissue and complete the electrical circuit. The device is washable using conventional detergents without adverse effect on the conductivity of the device.

The garment electrodes provide a snug elastic fit based upon the 37% elongation characteristic of the yarn used in the construction.

## F. TESTING

Bench testing has been done with this device demonstrating that it meets design controls.

Comparative testing was done between the TheraKnit garments and the predicate devices for resistance measurement and comparison.

## G. CONCLUSIONS

Design specifications, comparison to predicate device specifications and testing has demonstrated that this TheraKnit device meets design requirements and is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2005

Neurotron Medical, Inc.
c/o Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo Minnesota 55313

Re: K053214/S1
Trade/Device Name: Theraknit Garments
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: December 2, 2005
Received: December 5, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

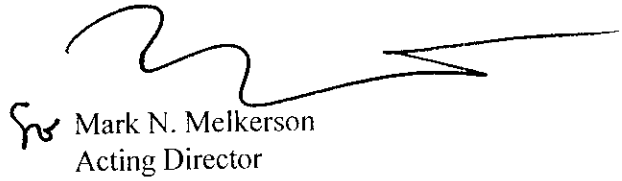
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K053214

Device Name: TheraKnit

Indications For Use:

The TheraKnit Garment Electrodes are cutaneous electrodes to be used with legally marketed TENS stimulating device. The knitted garment electrodes will deliver the stimulation signals generated by the stimulator to the body surface with which they are in contact. These body parts can include hand (glove), feet (socks), elbow or knee (sleeve), arm, leg, shoulder, back (pads).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053214